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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,921	11/03/2003	Dennis M. Treu	T4342-14521US01	3896

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
12/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/699,921	TREU, DENNIS M.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-53 and 70-80* is/are pending in the application.

4a) Of the above claim(s) *76 and 77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-53,70-75 and 78-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the reply filed 7/28/08, applicant amended claims 36 and 53, cancelled claims 54-69, and added new claims 70-80. Claims 19-53 and 70-80 are currently pending.

Election/Restrictions

2. Newly submitted claims 76 and 77 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 76-77 are drawn to the use of an RF transmitter without a corresponding receiver to produce a one-way signal. The previously presented claims were drawn to a system that uses an opto-isolator. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 76 and 77 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 19-53, 70, 71, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. (US 6,641,533) in view of Gilcher (US 6,113,554). Causey, III et al. (hereafter Causey) discloses a medical treatment device that can be connected to a computer (monitor unit) 6, the system comprising a treatment unit 400, a monitor unit 6, said treatment unit 400 comprising an infusion pump that delivers a medical treatment to a patient. The treatment unit 400 comprises a control panel (see Figure 7) having user-accessible controls. The monitor unit 6 is capable of receiving data from the treatment unit 400 and sensors via a common control unit (200, 300) (Column 23, Lines 49-52) and outputting at least data relating to the status of the treatment being delivered on a display portion 12. Additionally, the monitor unit is capable of outputting a variety of treatment information including graphical information, sensor data, and data that is not shown on the treatment device. Regarding the one-way transmission of data, Causey, III et al. further discloses that the computer 6 (monitoring portion) is capable of receiving data from the treatment unit 400 via a medical device module 200 for analysis (Column 23, Lines 49-52 and Figure 10), but does not disclose the computer 6 transmits data back to the medical device module 200 (as demonstrated by the one-way arrow to the communication station in Figure 10). Therefore, Causey, III et al. discloses a one-way communication channel between the treatment unit (400 by way of 200) and the monitoring device 6, such that the treatment machine 400 is not affected by a data-processing software being operated by the monitor device 6. Causey also disclose that the treatment unit 400 and monitor unit 6 are connected to a common control unit (200, 300) (see Figures 7 and 10). The

common control panel (200, 300) is capable of controlling and receiving data from the treatment unit 400, as well as transferring said data to the monitoring unit 6. Because the monitoring unit 6 does not transmit data back to the common control unit (200, 300), as shown by the one-way arrow in Figure 10, any signals from the monitor unit 400 are prevented from affecting a state of the treatment unit 400. With respect to Claim 54, Causey further discloses that the monitor unit receives data via a one-way communication signal, and may not transmit data back to the treatment unit (Figure 10). The computer receives data that has been processed by the medical device module. Therefore, the data received by the computer is not real-time.

Causey discloses the device substantially as claimed, but does not disclose that the treatment unit and monitor unit are permanently attached together and housed within a common housing.

Gilcher et al. disclose a blood collection system comprising a housing 14 that houses a monitor unit 10 and a treatment unit 12. The housing further comprises a control panel 72. The use of a unitary construction allows the monitor unit 10 and the treatment unit 12 to be simultaneously monitored and prevents the need for wireless communication between devices. Furthermore, the use of a one-piece construction instead of multiple, distinct parts is merely a matter of obvious engineering choice. See MPEP § 2144.04. Therefore, it would have been obvious to one skilled in the art at the time of medical treatment device of Causey, III et al. with the unitary housing of Gilcher et al. in order to provide a simplified unit for medical treatment that does not comprise several parts. Furthermore, Causey et al. disclose that the device was broken into

components in order to improve price and upgradeability, and that some devices would preferably be combined into a single device. The components that comprise the medical treatment device are more than capable of functioning as a singular unit in a common housing.

5. Claims 19-53, 70-75, and 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGrath (US 4,216,462) in view of Markham (US 5,401,394).

6. With respect to Claims 19, 21, 23-32, 34-38, 40-49, 51-53, 70-75, and 79, McGrath teaches a medical treatment system comprising a fixed treatment unit 12 with user-accessible controls configured to control the administration of a medical treatment of a patient provided by the treatment unit and indicators configured to show status information related to the treatment. The system also comprises a fixed monitor unit 18 with a display that receives and outputs information related to the treatment. The treatment unit supplies data signals to a central control station, which then perform calculations and supplies a data output to the monitor unit. The monitor unit is capable of displaying graphical output or text such as sensor readings, troubleshooting information, or any other information processed by the control station. When data is passed to the central control station, it passes through an optical isolation device (an opto-isolator) to isolate the electric currents between parts of the system, thereby ensuring that only a one-way flow of information occurs from the treatment system to the control system. McGrath teaches the system being separated by an opto-isolator wherein the treatment unit sends signals to the control station over a one-way

communication channel substantially as claimed, but does not specifically teach that the *monitor* unit is connected to the control system by a one-way communication channel.

Markham teaches a system for monitoring the status of an ultraviolet bulb in a water treatment system. The treatment system emits a logic signal when an abnormally high or low voltage is detected (see abstract). The logic signal is passed from the treatment unit to a bulb status monitor circuit that monitors the status of the bulb. The monitor circuit comprises an opto-isolator 130 that electrically isolates the monitoring circuit from the rest of the system. Therefore, the monitor circuit is capable of receiving data from the treatment unit, but not capable of transmitting data back to the treatment unit. *The use of opto-isolators to isolate monitor units is well known in the art of basic electrical control systems, not only in the medical art, as a means for electronically isolating the monitor unit and preventing it from affecting the function of a treatment unit.* Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the medical control system of McGrath with Markham's isolation of the monitor unit from the rest of the system in order to provide a one-way communication channel between the treatment unit and the monitor unit, thereby allowing the monitor unit to receive data transmitted from the control station without affecting the operation of the treatment unit.

7. With respect to Claims 20, 22, 33, 39, 50, 78, and 80, McGrath and Markham reasonably suggest the device substantially as claimed, but do not specifically teach that all components of the system are permanently attached within a common housing,

such that a user may monitor the treatment unit and the monitor unit simultaneously. However, merely integrating a plurality of components does not constitute a patentable improvement in the art because doing so does not provide any novel functional advantages over the device taught by McGrath (See MPEP § 2144.04, V., B.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the treatment and monitoring system McGrath to make the treatment unit and monitoring unit part of the same integral housing in order to make both units accessible to the same user in a single location.

Response to Arguments

8. Applicant's arguments filed 7/28/08 with respect to the rejection over Causey in view of Gilcher have been fully considered but they are not persuasive.

First, applicant argues that Causey does not teach a one-way communication mechanism. A "one-way communication mechanism, however, may be any communication system that is *capable* of sending a signal in only one direction. As discussed in the rejection above and in the previous arguments, Causey shows at least one embodiment wherein the communication mechanism of the treatment device sends a one-way communication signal. During this mode of operation, said communication mechanism does not receive (i.e. is prevented from receiving) data from the monitor unit.

Second, applicant argues that "Causey makes it quite clear that the medical device module 200 can be used to program and obtain data from infusion pump 400." This, however, is merely one mode of operation of the device.

Finally, applicant argues that the proposed modifications to Causey based on the teachings of Gilcher would be improper because it would be rendered unsatisfactory for its intended objective of remote testing. However, the mere integration of the individual components into an integral housing does not constitute a patentable improvement in the art. One of ordinary skill in the art at the time of invention would have been motivated to integrate the units into a single housing in order to allow the user to have access to all units at a single location. The mere use of wireless communication between the units does not mean that the treatment unit and monitoring unit can not be combined into a single housing.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761
/Leslie R. Deak/
Primary Examiner, Art Unit 3761
5 December 2008